

05/12/2006 FRI 13:02 FAX

001/018

RECEIVED
CENTRAL FAX CENTER

MAY 12 2006

Johnson & Johnson

F A C S I M I L E

| | | | |
|---|--------------------------|---------------|---------------------------|
| TO: | Commissioner for Patents | DATE: | May 12, 2006 |
| FAX: | (571) 273-8300 | Re: | END5293USNP |
| FROM: | Andy Ulmer, Esq. | No. of PAGES: | Including Cover Page : 18 |
| If There Is Any Problem With This Fax, Please Contact: Kimberly Moses at 513-337-7019 | | | |

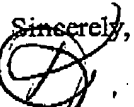
Patent Office:

I am transmitting the following documents:

| | | | |
|-------------------------------------|--|---|---------|
| <input checked="" type="checkbox"/> | This cover Sheet | 1 | page(s) |
| <input checked="" type="checkbox"/> | Amendment to Office Action & Extension of Time | 8 | page(s) |
| <input type="checkbox"/> | Corrected Amendment to Office Action | | page(s) |
| <input checked="" type="checkbox"/> | Copy of Office Action | 9 | page(s) |
| <input type="checkbox"/> | Petition for Revival Unintentionally | | page(s) |
| <input type="checkbox"/> | Extension of Time | | page(s) |
| <input type="checkbox"/> | Terminal Disclaimer | | page(s) |
| <input type="checkbox"/> | Notice of Non-Compliant | | page(s) |
| <input type="checkbox"/> | Notice of Appeal | | page(s) |
| <input type="checkbox"/> | Change of Correspondence Address | | page(s) |
| <input type="checkbox"/> | RCE | | page(s) |
| <input type="checkbox"/> | Translations to cited references | | page(s) |

Thank you for your help. Please contact me if you have problems with the transmission.

Sincerely,


Kimberly M. Moses
Executive Legal Assistant
Dean L. Garner and Gerry S. Gressel
Johnson & Johnson Law Department
Email: kmoses@eesus.jnj.com
513-337-7019 Tel
513-337-4030 Fax

CONFIDENTIALITY NOTICE

This message is intended only for the individual or entity to which it is addressed and may contain information that is privileged, confidential, and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, or the employee or agent responsible for delivering the message solely to the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return to us at the above address via the U.S. postal service.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------|-------------|----------------------|---------------------|------------------|
| 10/808,078 | 03/24/2004 | Mark Tsontou | END-5293 | 7086 |
| 27777 | 7590 | 01/24/2006 | EXAMINER | |
| PHILIP S. JOHNSON | | | ROY, ANURADHA | |
| JOHNSON & JOHNSON | | | ART UNIT | |
| ONE JOHNSON & JOHNSON PLAZA | | | PAPER NUMBER | |
| NEW BRUNSWICK, NJ 08933-7003 | | | 3736 | |

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
 JAN 27 2006
 I&J PAT. DKT. SECTION

Office Action Summary

Application No.

10/808,078

Applicant(s)

TSONTON ET AL.

Examiner

Anuradha Roy

Art Unit

3736

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/03)
 Paper No(s)/Mail Date 3/24/04
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

U.S. Patent and Trademark Office
 PTOL-326 (Rev. 1-04)

Office Action Summary

Part of Paper No./Mail Date 20060118

Application/Control Number: 10/808,078
Art Unit: 3736

Page 2

DETAILED ACTION**Claim Objections**

Claims 17, 18, & 20 are objected to because of the following informalities: Claim 17 & 18 state dependence on Claim 19. Additionally, Claim 20 states dependence on Claim 20. Examiner believes this was an inadvertent error and Applicant intended for Claims 17 & 18 to be dependent on Claim 16, and Claim 20 to be dependent on Claim 19; therefore, the claims have been examined in this manner. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 & 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al. (US Publication No. 2003/0028094).

Regarding claim 1, Kumar et al. discloses a biopsy device suitable for use with a magnetic resonance imaging machine, said device comprising an elongated needle (1810) for receiving tissue therethrough, the needle comprising: a distal needle segment (1811) comprising a tissue receiving port (1812), the distal needle segment formed of a first material [0045] that does not interfere with MRI imaging of a portion of the distal needle segment associated with the tissue receiving port; a proximal needle segment

Application/Control Number: 10/808,078
Art Unit: 3736

Page 3

(1890 & 1820) disposed proximally of the tissue receiving port, the proximal needle segment formed at least in part of a second material different from said first material [0188].

With regard to claims 6-8, Kumar et al. discloses a proximal needle segment, wherein the second material comprises a metal and is non-magnetic [0186] and is selected from the group comprising aluminum, aluminum alloys, stainless steel, titanium, titanium alloys, and combinations thereof [0186]. Examiner contends wire is a form of metal according to the definition found in the Webster dictionary online.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4 & 9-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Huitema et al. (US Patent No. 6,626,849).

Regarding claims 2, 3, 16 -18, & 19, Kumar discloses a biopsy device suitable for use with a magnetic resonance imaging machine and comprising: a distal needle segment (1811) comprising a tissue receiving port (1812) communicating with a cutter lumen, the distal needle segment formed of a first material [0045]; a proximal needle segment (1890 & 1820) formed at least in part of a metal [0188], the proximal needle segment providing at least a portion of the cutter lumen (Figure 18 & 19), and wherein

Application/Control Number: 10/808,078
Art Unit: 3736

Page 4

said metal is spaced proximally at least about 0.5 inch from a proximal edge of said tissue receiving port [0079]. Kumar, however, does not teach of the first material being a non-metallic material. However, Huitema et al. teaches of a non-metallic and nonmagnetic material (Column 4, lines 25-31) for the distal region of the needle. It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Huitema et al. to utilize a non-metallic and non-magnetic material on the needle with Kumar et al. in order to prevent an obscured image of the lesion by the needle.

"The image of the lesion will show the metal probe, and this is problematic because the image of the probe can obscure the image of the lesion. Therefore, there has been a desire to have a generally non-metallic biopsy probe of the type described above." (Column 2, lines 59-63)

Regarding claim 4, Huitema et al. further discloses a distal needle segment, wherein the first material comprises a liquid crystal polymer (Column 4, lines 25-31).

With regard to claims 9-11, Huitema et al. discloses a device further comprising a distal piercing tip (Figure 1 & 60) disposed distal of the tissue receiving port, wherein the distal piercing tip comprises a non-metallic material and is selected from the group comprising ceramics and glasses (Column 7, lines 30-34).

In regards to claim 12, Huitema et al. discloses a device, wherein the proximal needle segment (33) and the distal needle segment provide a continuous, smooth cutter lumen (32).

Application/Control Number: 10/808,078
Art Unit: 3736

Page 5

In regards to claim 13, Huitema et al. discloses a device, wherein the proximal needle segment and the distal needle segment provide a continuous vacuum lumen (34).

In regards to claim 14, Huitema et al. discloses a device, wherein the needle comprises at least passage (36) extending from the vacuum lumen to an outer surface of the needle.

In regards to claim 15, Huitema et al. discloses a device, wherein the distal needle segment comprises a plurality of passages (Figure 4 & 23) extending from the vacuum lumen to the outer surface of the needle.

With regard to claim 20, Huitema et al. discloses a device, wherein the distal needle segment comprises at least a portion of a vacuum lumen (Figure 4 & 34).

Additional Claim Rejections - 35 USC § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. in view of Sapatova et al. (US Publication No. 2003/0203140).

Kumar et al. discloses the aforementioned element of a biopsy device. Kumar et al., however, does not directly disclose a melt flow index of at least about 15 grams/minute. However, Sapatova et al. teaches of a melt flow index of at least about 15 grams/minute ([0015] & [0047]). It would have been obvious to one having ordinary skill in the art at the time of the invention in view of Sapatova et al. to have a melt flow index of at least 15 grams/minute with Kumar et al. in order to allow for the "implementation of multi-cavitation tools, and a commensurate increase in productivity" [0047].

Application/Control Number: 10/808,078
Art Unit: 3736

Page 6

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rhad et al. (US Publication No. 2003/0109801) discloses a MRI compatible surgical device and Karasawa (US Patent No. 5,738,632) discloses material in used for MRI apparatus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

Max Hindenburg
MAX HINDENBURG
PATENT EXAMINER
MAY 12 2006

MAY 12 2006

PTO/SB/06A (08-00)
Approved for use through 10/31/2002. OMB 0551-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

| | | |
|---|-------------------------------|--------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <small>(use as many sheets as necessary)</small> Sheet 1 of 1 | Application Number | Not Yet Assigned |
| | Filing Date | March 24, 2004 |
| | First Named Inventor | Mark Tsontou et al |
| | Group Art Unit | Not Yet Assigned |
| | Examiner Name | Not Yet Assigned |
| | Attorney Docket Number | END-5293 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|--------------------------|----------------------|--------------------------------------|--|--|--|
| Examiner Initials | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant, passages or relevant figures appear |
| | | Number | Kind Code ² (if known) | | | |
| AL | | 5,526,822 | | Burbank et al. | 06/18/1998 | ALL |
| AL | | 5,895,401 | | Daum et al. | 04/20/1999 | ALL |
| AL | | 6,086,544 | | Hibner et al. | 07/11/2000 | ALL |
| AL | | 6,620,111 | B2 | Stephens et al. | 09/16/2003 | ALL |
| AL | | 6,626,849 | B2 | Huitama et al. | 09/30/2003 | ALL |
| AL | | 6,638,235 | B2 | Miller et al. | 10/28/2003 | ALL |
| AL | | 2003/0199753 | A1 | Hibner et al. | 10/23/2003 | ALL |
| AL | | 2003/0199754 | A1 | Hibner et al. | 10/23/2003 | ALL |
| AL | | 2003/0199785 | A1 | Hibner et al. | 10/23/2003 | ALL |
| AL | | 2003/0109803 | A1 | Huitama et al. | 06/12/2003 | ALL |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|--------------------------|-------------------------|---------------------|------------------------|--|--|--|----------------|
| Examiner Initials | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear | T ² |
| | | Office ³ | Number ⁴ | Kind Code ⁵ | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| | | | |
|-----------------------|---------------------|--------------------|------------|
| Examiner Signature | <i>Mark Tsontou</i> | Date Considered | 11/18/2006 |
|-----------------------|---------------------|--------------------|------------|

¹EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

²Unique citation designation number. ³See attached Kinds of U.S. Patent Documents. ⁴Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁷Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1480, Alexandria, VA 22313-1450

| | | | |
|-----------------------------------|---------------------------------------|--|-------------|
| Notice of References Cited | Application/Control No. 10/808,078 | Applicant(s)/Patent Under Reexamination TSONTON ET AL. | |
| | Examiner Anuradha Roy | Art Unit 3736 | Page 1 of 1 |

U.S. PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Name | Classification |
|---|---|--|-----------------|------------------|----------------|
| * | A | US-2003/0028094 | 02-2003 | Kumar et al. | 600/410 |
| * | B | US-6,626,849 | 09-2003 | Huitema et al. | 600/584 |
| * | C | US-2003/0203140 | 10-2003 | Sapatova et al. | 428/35.7 |
| * | D | US-2003/0109801 | 06-2003 | Rhad et al. | 600/584 |
| * | E | US-5,738,632 | 04-1998 | Karasawa, Masaru | 600/410 |
| | F | US- | | | |
| | G | US- | | | |
| | H | US- | | | |
| | I | US- | | | |
| | J | US- | | | |
| | K | US- | | | |
| | L | US- | | | |
| | M | US- | | | |

FOREIGN PATENT DOCUMENTS

| * | | Document Number Country Code-Number-Kind Code | Date MM-YYYY | Country | Name | Classification |
|---|---|--|-----------------|---------|------|----------------|
| | N | | | | | |
| | O | | | | | |
| | P | | | | | |
| | Q | | | | | |
| | R | | | | | |
| | S | | | | | |
| | T | | | | | |

NON-PATENT DOCUMENTS

| * | | Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) |
|---|---|---|
| | U | |
| | V | |
| | W | |
| | X | |

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
 Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

U.S. Patent and Trademark Office
 PTO-892 (Rev. 01-2001)

Notice of References Cited

Part of Paper No. 20060118